PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

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NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)

(PCT Rule 44bis.1(c))

To:

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Date of mailing *(day/month/year)* 27 October 2011 (27.10.2011)		
Applicant's or agent's file reference ART053PCT		IMPORTANT NOTICE
International application No. PCT/US2010/031602	International filing date *(day/month/year)* 19 April 2010 (19.04.2010)	Priority date *(day/month/year)* 17 April 2009 (17.04.2009)
Applicant ARTHROSURFACE INCORPORATED et al		

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference ART053PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2010/031602	International filing date *(day/month/year)* 19 April 2010 (19.04.2010)	Priority date *(day/month/year)* 17 April 2009 (17.04.2009)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ARTHROSURFACE INCORPORATED		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 18 October 2011 (18.10.2011)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: EDMUND PFLEGER
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	18 JUN 2010
Applicant's or agent's file reference ART053PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/031602	19 April 2010	17 April 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/56 (2010.01)
USPC - 606/79

Applicant ARTHROSURFACE INCORPORATED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	01 June 2010	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Tallarida et al. (hereinafter Tallarida) in view of Chudik.

Regarding claim 1, Tallarida discloses a method for repairing a defect on a portion of an articular surface (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system), said method comprising: securing a guide pin to said articular surface of said glenoid proximate to said defect (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically), wherein said guide pin defines a working axis and said working axis is positioned at an angle A relative to the articular surface (Para. [0108] shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A; when compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working axis 20A used to define the implant geometry), wherein angle A is less than or equal to 90 degrees (Para. [0128] ...accomplished by adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool); advancing an excision device over said guide pin (Para. [0110] As illustrated in Fig. 16, when fitted with a cutting blade 121, and with the guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes through a closely sized hole 116 in the cutting blade, the blade's position becomes fully constrained), wherein said excision device includes a cannulated shaft (Para. [0108] In the embodiment shown in Fig. 15a, compass instrument 120 includes handle 110, a cannulated shaft 111 that extends through the handle, and a cannulated distal offset arm 112...) and at least one cutter extending radially outwardly from said cannulated shaft, wherein said at least one cutter is generally aligned in a single plane extending along a longitudinal axis of said cannulated shaft (Para. [0110] As illustrated in Fig. 16, when fitted with a cutting blade 121, and with the guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes through a closely sized hole 116 in the cutting blade, the blade's position becomes fully constrained), but fails to explicitly disclose the method wherein the articular surface is of a patient's glenoid and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) wherein the articular surface is of a patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft) and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (FIG. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to include repair of a defect at a patient's glenoid wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 2, Tallarida in view of Chudik discloses the method of claim 1. Tallarida further discloses the method wherein said guide pin is configured to be disposed at an angle A relative to the articular surface, wherein 90 degrees > A > 45 degrees (Para. [0128] adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool. This also allows for a correction of the implant geometry, to compensate for any non-perpendicular placement of the guide pin with respect to the articular surface). Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to dispose the guide pin at a desired angle relative to a plane in an articular surface repair, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding claim 3, Tallarida in view of Chudik discloses the method of claim 1. Tallarida discloses the method further comprising removing said guide pin and placing an implant in said excision site (Para. [0048] Fig. 8b is a sagital view of the exemplary fixation screw and hex-shaped proximal extension of FIG. 8a implanted in the defect after removal of an exemplary socket type driver and guide pin).

Regarding claim 4, Tallarida in view of Chudik discloses the method of claim 1. Tallarida further discloses the method wherein said defect is disposed proximate to a perimeter of said articular surface and wherein said excision site extends to said perimeter (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically; Figs. 8A, 11A, and 11B)).

Regarding claim 5, Tallarida in view of Chudik discloses the method of claim 4. Tallarida further discloses the method wherein said defect comprises a missing portion of said perimeter of said articular surface (Para. [0098] As an overview, Fig. 1 shows a surgically implanted articular joint surface repair system consistent with the present invention. As shown, the assembled fixation device includes fixation screw 10, implant 40, and anchoring pin 5, implanted in the defect in the medial femoral chondral surface 55 of knee 50. Implant 40 is configured so that bearing or bottom surface 41 of the implant reproduces the anatomic contours of the surrounding articular surface of the knee 50).

Regarding claim 6, Tallarida in view of Chudik discloses the method of claim 1. Tallarida further discloses the method wherein said at least one cutter includes a first cutter and a second cutter (Para. [0026] ... a cannulated distal offset arm configured to serve as a linearly adjustable mounting tool for a series of cutting blades, boring blades, or measuring probes), which extend generally radially outwardly from the cannulated shaft at an angle of approximately 180 degrees from each other (see cutting blade 121 at Fig. 16; Paras. [0109] and [0110]).

Regarding claim 7, Tallarida in view of Chudik discloses the method of claim 1. Tallarida fails to explicitly disclose the method wherein said at least one cutter has a cross-sectional thickness of 0.5 mm to 3.0 mm. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a thickness in the range of 0.5 mm to 3.0 mm, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 8, Tallarida discloses a method for repairing a defect on a portion of an articular surface (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system), said method comprising: securing a guide pin to said articular surface of said glenoid proximate to said defect (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically), wherein said guide pin defines a working axis and said working axis is positioned at an angle A relative to the articular surface (Para. [0108] shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A; when compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working axis 20A used to define the implant geometry), and advancing an excision device over said guide pin (Para. [0110]), wherein said excision device includes a cannulated shaft and at least one cutter extending radially outwardly from said cannulated shaft (Paras. [0108] through [0110]), wherein said at least one cutter is generally aligned in a single plane extending along a longitudinal axis of said cannulated shaft (Para. [0110]), but fails to explicitly disclose the method for an articular surface of a patient's glenoid, wherein angle A is selected to avoid contact with a corresponding humerous and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) wherein the articular surface is of a patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft) wherein angle A is selected to avoid contact with a corresponding humerous (Chudik Para. [0116] the transhumeral protective sheath 38 of the present invention provides protection for the bone within which the transhumeral portal sits) and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to include repair of a defect at a patient's glenoid to avoid contact with a patient's humerous wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient and avoiding undesired damage to surrounding tissues in the area of resurfacing.

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Supplemental Box

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Regarding claim 9, Tallarida discloses a system for repairing a defect on a portion of an articular surface (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system), said system comprising: a guide pin configured to be secured into bone beneath the articular surface of the glenoid (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically); an excision device (Para. [0110]) including: a cannulated shaft configured to be advanced over said guide pin (Para. [0108] ...in Fig. 15a, compass instrument 120 includes handle 110, a cannulated shaft 111 that extends through the handle, and a cannulated distal offset arm 112...), and at least one cutter (Para. [0110]); and an implant including a load bearing surface and a bone facing surface (Para. [0022] define a three dimensional surface matched to the bearing surface geometry to be implanted and reproduce the anatomic contours mapped; Para. [0023]), wherein said load bearing surface exhibits a contour substantially corresponding to the contour of the articular surface (Paras. [0022] and [0023]), but fails to explicitly disclose the system at an articular surface of a patient's glenoid and the cutter configured to form a generally hemispherical excision site in said glenoid about said guide pin and wherein said at least one cutter has a cross-sectional thickness of 0.5 mm to 3.0 mm and said at least one cutter includes a cutting surface having a generally arcuate shape sweeping towards a proximal end of said cannulated shaft and said generally hemi-spherical bone facing surface is configured to be received in said generally hemispherical excision site. However Chudik teaches a system for shoulder replacement surgery (Chudik Abstract) wherein the articular surface is of a patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft) and the cutter configured to form a generally hemispherical excision site in said glenoid about said guide pin and said generally hemi-spherical bone facing surface is configured to be received in said generally hemispherical excision site (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Tallarida to include repair of a defect at a patient's glenoid to avoid contact with a patient's humerous wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient and avoiding undesired damage to surrounding tissues in the area of resurfacing. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a thickness in the range of 0.5 mm to 3.0 mm, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a cutting surface having a generally arcuate shape, since a mere change in the shape of a device involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 10, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said guide pin is configured to be disposed at an angle A relative to the articular surface, wherein angle A is < 90 degrees (Para. [0128] adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool. This also allows for a correction of the implant geometry, to compensate for any non-perpendicular placement of the guide pin with respect to the articular surface). Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to dispose the guide pin at a desired angle relative to a plane in an articular surface repair, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 11, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said guide pin is configured to be disposed at an angle A relative to said articular surface, wherein 90 degrees >= A >= 45 degrees (Para. [0128] ... accomplished by adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool).

Regarding claim 12, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said at least one cutter includes a first cutter and a second cutter (Para. [0026] ... a cannulated distal offset arm configured to serve as a linearly adjustable mounting tool for a series of cutting blades, boring blades, or measuring probes), wherein said first and second cutters extend generally radially outwardly from said cannulated shaft at an angle approximately 180 degrees from each other (see cutting blade 121 at Fig. 16; Paras. [0109] and [0110]). Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to position the cutting blades 180 degrees opposite each other, since a mere rearrangement of parts of a device involves only routine skill in the art and for the purpose of providing dynamic balance to the device and thereby facilitate stability.

Regarding claim 13, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein an overall radius R, of said at least one cutter defines a radius of said excision site created by said excision device (Para. [0027] With the guide pin advanced through the instrument shaft, when fitted with a blade, a fixed length from the rotational or reference axis to the cutting blade's cutting surface is established. This defines the radius that is effected as the instrument is rotated around the guide pin, and corresponds to the overall diameter of the implant. This sharp cutting blade is used to circumscribe and cleanly cut the surrounding articular cartilage).

Regarding claim 14, Tallarida in view of Chudik discloses the system of claim 13. Tallarida further discloses the system wherein said overall radius R, substantially corresponds to a radius R, of said implant (Para. [0027]).

Regarding claim 15, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said impact guide includes an impact guide arm and said impact device includes a proximal end and a distal end (Para. [0110] cutting blade 121), and said proximal end of said impact device is configured to be disposed generally parallel to said impact guide arm when said distal end is received in said impact slot (Paras. [0108] and [0110]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding claim 16, Tallarida in view of Chudik discloses the system of claim 9 [as best understood]. Tallarida further discloses the system wherein said depth D substantially corresponds to a height H of said implant (Para. [0106]).

Regarding claim 17, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said load bearing surface comprises a beveled region disposed about a perimeter of said load bearing surface (Fig. 19d at notch 386; Paras. [0127], [0142], and [0143]).

Regarding claim 18, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said bone facing surface comprises at least one lip, protrusion and/or rib configured to increase a mechanical connection between said implant and bone within said excision site (Paras. [0142] and [0143]; Para. [0127] As shown in Fig. 19b, outer diameter 190 may include a slight outward taper or protrusion 197 along the diametrical surface to enhance load bearing or load transfer properties of the implant to surrounding bone).

Regarding claim 19, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said implant comprises at least one keel extending generally outwardly from said bone facing surface (Para. [0127] As shown in Fig. 19b, outer diameter 190 may include a slight outward taper or protrusion 197 along the diametrical surface to enhance load bearing or load transfer properties of the implant to surrounding bone).

Regarding claim 20, Tallarida in view of Chudik discloses the system of claim 19. Tallarida further discloses the system wherein said at least one keel includes a protrusion disposed about a distal end of a base region (Para. [0127] and Fig. 19b).

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.